Bristol-Myers Squibb
Pharmaceutical Research Institute

P.O. Box 4000 Princeton, NJ 08543-4000
Tel: 609 252-5992 Fax: 609 252-3619
laurie.smaldone@bms.com

Laurie Smaldone, M.D.
Senior Vice President
Global Regulatory Sciences

July 29, 2002

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1652; Proposed Rule, *Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format [67 Federal Register 22367 (May 3, 2002)]*

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2001 alone, Bristol-Myers Squibb dedicated $2.1 billion for pharmaceutical research and development activities. The company has nearly 6,000 scientists and doctors committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises more than 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on this FDA proposal to mandate the electronic submission of labeling content for NDAs, certain BLAs, ANDAs, supplements, and annual reports.

We commend the U.S. FDA for establishing a mechanism to retain the integrity of labeling content throughout the review process while introducing certain capabilities that will enhance the accuracy and speed of labeling review. In particular we agree with the Agency's current preference for PDF format while providing the flexibility to take advantage of future improvements in computer technology and software design. Further, we endorse the Agency's action to exempt the submission of labeling content under this proposed rule from certain requirements imposed by Part 11 regulations.

Recognizing the essential purpose of this proposed rule being to facilitate the quality and efficiency of labeling review, we would like to recommend a modification with respect specifically to annual reports. Given that labeling revisions to mature products are infrequent and often insubstantial in nature (e.g., editorial, format changes), conversion of labeling elements

for these products to electronic format in order to comply with the proposed mandate for annual reports represents a burden not justified by the objective of this rule. Our recommendation, therefore, is to have electronic labeling format continue as an option for annual report submissions for products where the labeling has not been revised (beyond minor editorial changes) during the previous year.

Specifically, modification should be made to proposed §314.81 *Other postmarketing reports, (iii)*

Labeling (b): "The content of labeling required under §201.100(d)(3) of this chapter (i.e., the package insert or professional labeling), including all text, tables, and figures, must be submitted in electronic format. However, if the product's labeling has not been revised beyond editorial changes during the period covered by the report, submission in electronic format is optional...."

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendation.

Sincerely,

Laurie Smaldone

Laurie Smaldone, M.D.
Senior Vice President, Global Regulatory Sciences